# Exhibit 18

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

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FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2001
OR

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from _____ to _____
Commission file number 1-9898

Organogenesis Inc.

(Exact name of registrant as specified in its charter)

| Delaware | 04-2871690 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

150 Dan Road, Canton, MA 02021
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 575-0775

Securities registered pursuant to Section 12(b) of the Act:

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| Common Stock, $.01 value | American Stock Exchange |

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ( X ) No ( )

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ( )

The approximate aggregate market value of voting stock held by non-affiliates of the registrant was $64,706,000 based on the last reported sale price of the company's common stock on the American Stock Exchange as the close of business on March 25, 2002. There were 44,316,276 shares of common stock outstanding as of March 25, 2002, which excludes 250,000 treasury shares.

DOCUMENTS INCORPORATED BY REFERENCE

| Document | Part of Form 10-K into which incorporated |
|---|---|
| Portions of the Registrant's Definitive Proxy Statement for its 2002 Annual Meeting of Stockholders | III |

With the exception of the portions of the Definitive Proxy Statement for the registrant's 2002 Annual Meeting of Stockholders expressly incorporated into this Report by reference, such document shall not be deemed filed as a part of this Annual Report on Form 10-K.

PART I

This Form 10-K contains forward-looking statements that involve risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "plans", "anticipates", "believes", "estimated", "predicts", "potential", "continue", or the negative of such terms or other comparable terminology. Forward-looking statements include information on:

- Our business outlook and future financial performance;
- Anticipated profitability, revenues, expenses and capital expenditures;
- Anticipated research, development, clinical, regulatory and reimbursement progress;
- Future funding and expectations as to any future events; and
- Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-K. The risk and other factors noted under the section "Risk factors" beginning on page 6 and throughout this Form 10-K could cause our actual results to differ materially from the results contained in any forward-looking statements. We are under no duty to update any of the forward-looking statements after the date of this report on Form 10-K to conform forward-looking statements to actual results.

Item 1. Business

Organogenesis Inc. designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We were the first company to develop, manufacture and gain US Food and Drug Administration ("FDA") approval for a mass-produced product containing living human cells. Our lead product, Apligraf(R) living skin substitute, is FDA approved and marketed in the US for two uses: treatment of healing-resistant venous leg ulcers, approved in May 1998, and treatment of healing-resistant diabetic foot ulcers, approved in June 2000. Novartis Pharma AG ("Novartis") has exclusive global Apligraf marketing rights. Our FortaFlex(TM) bioengineered collagen matrix product line includes FortaPerm(TM) tissue support product and FortaGen(TM) tissue repair product. Both FortaPerm and FortaGen are being sold by our sales and marketing team.

Organogenesis was organized as a Delaware corporation in 1985. Our principal office is located at 150 Dan Road, Canton, Massachusetts 02021. The telephone number is 781/575-1570 and the fax number is 781/575-0440. Our website address is www.organogenesis.com.

Business Strategy

Our goal is to expand our position as a leading tissue repair and regeneration company. Key elements of our strategy include:

- Accelerate market penetration of Apligraf: We support the efforts of Novartis, which has global Apligraf marketing rights, to expand the use of Apligraf in the wound care market. Our participation includes raising the awareness of Apligraf's applications and benefits among medical thought leaders by publishing Apligraf-related articles in leading medical journals, as well as

Apligraf(R) is a registered trademark of Novartis.

participating in professional forums where advances in new treatments are discussed. We also seek to expand the indications for which Apligraf has marketing approval.

- Improve our manufacturing process for Apligraf: We are continually working to improve our Apligraf manufacturing process to decrease costs and increase our production capacity. For example, we have introduced semi-automated equipment for segments of the process to increase consistency and reliability and have streamlined procedures to increase efficiency.

- Develop new products utilizing our living cell and bioengineered collagen matrix technologies: We have recently launched two bioengineered collagen matrix products - FortaPerm tissue support and FortaGen tissue repair. We expect to introduce additional products during 2002. We have under development additional bioengineered collagen matrix, as well as living cell, product candidates.

- Selectively utilize strategic relationships: We intend to efficiently develop and commercialize our products by maintaining a flexible strategy for outsourcing our development, manufacturing and marketing activities. Our strategy focuses our internal efforts on proprietary areas, including the manufacture of Apligraf and certain research and development programs. We seek to outsource functions that are beyond our capacity or where it is more cost effective to do so. For example, we entered into an agreement with Novartis in January 1996 under which Novartis is responsible for the worldwide marketing of Apligraf and we are responsible for its manufacture. Alternatively, we have built our own sales force to sell certain products, including FortaPerm and FortaGen, to targeted markets.

Products and Product Pipeline

| Product or Product Under Development | Indication/Potential Uses | U.S. Development and Regulatory Status | Commercialization |
|---|---|---|---|
| **Apligraf** | | | |
| Apligraf living skin substitute | Diabetic foot ulcers | On market | Novartis |
| | Venous leg ulcers | On market | Novartis |
| | Skin surgery wounds | Pivotal trial | Novartis |
| **Fortaflex Products** | | | |
| FortaPerm(TM) tissue support | Vaginal prolapse; urinary incontinence; various reconstructive and aesthetic plastic surgery procedures | On market | Internal sales force |
| FortaGen(TM) tissue repair | Complex/recurrent hernias; ostomy reinforcement; muscle flap donor sites | On market | Internal sales force |
| PuraPly(TM) wound dressing | Acute and chronic partial and full-thickness wounds | Pilot Marketing underway by Royce(R) | Royce Medical Company and internal sales force |

Royce(R) is a registered trademark of Royce(R) Medical Company.

| Product or Product Under Development | Indication/Potential Uses | U.S. Development and Regulatory Status | Commercialization |
|---|---|---|---|
| | Other Research and Development Programs | | |
| FortaFlex Product<br>rotator cuff repair product | Rotator cuff repair procedures | Marketing clearance granted | Biomet, Inc. |
| FortaFill(TM)<br>tissue augmentation | Tissue augmentation procedures, such as facial augmentation | Under development | Expect to use internal sales force |
| Revitix(TM)<br>regenerative skin complex | Following laser resurfacing and deep chemical peel procedures | Under development | Expect to use internal sales force |
| Vitrix(TM)<br>living dermal replacement product | Deep diabetic foot ulcers and deep pressure sores | Pilot study in deep diabetic foot ulcers | Novartis has right to purchase option to negotiate license |
| other living wound healing products | | In research | |

## Products and Programs

We are utilizing our expertise in living cells and natural connective tissue in our product development. In addition to Apligraf, FortaPerm and FortaGen, we have developed PuraPly(TM) wound dressing product and, with Biomet, a rotator cuff repair product. Development programs include FortaFill(TM) soft tissue augmentation product candidate, Revitix(TM) regenerative skin complex and Vitrix(TM) living dermal replacement product candidate, as well as other living tissue replacements.

### Apligraf living skin substitute

Apligraf was the first mass-produced product containing living human cells to gain FDA marketing approval. Apligraf contains living human skin cells - keratinocytes and fibroblasts - organized in an epidermal and dermal layer. Apligraf is mass-produced, available to physicians on demand and does not require hospitalization for use.

Novartis has exclusive global Apligraf marketing rights. In 2001, we amended our license and supply agreement with Novartis to significantly increase the payments we receive for Apligraf units shipped and to provide funding support for certain facility investments and clinical development activities. We obtained FDA marketing approval of Apligraf in the US for use in the treatment of venous leg ulcers in 1998 and for use in the treatment of diabetic foot ulcers in 2000. Novartis also markets Apligraf in select international markets.

Current and Potential Markets -

Diabetic foot ulcers: Apligraf is FDA-approved for use in the treatment of healing-resistant diabetic foot ulcers. Apligraf has been shown to heal more of these ulcers, and heal them faster, than standard care alone. A common complication of diabetes, foot ulcers afflict up to 800,000 people in the US. Unhealed, these wounds can lead to life-threatening infections and do result in over 80,000 amputations per year. Foot ulcers are also a leading cause of hospitalization among diabetics. The treatment of diabetic foot ulcers and the expenses of diabetes-related amputations are estimated to cost the US healthcare system over $1 billion per year.

Venous leg ulcers: Apligraf is also approved and marketed in the US for the treatment of healing-resistant venous leg ulcers, chronic wounds caused by poor blood circulation. Apligraf has been shown to heal more of these ulcers, and heal them faster, than standard care alone. Venous leg ulcers afflict approximately 500,000 people in the US. They can take six months or longer to heal. Data have been published on the cost-effectiveness of Apligraf in the treatment of hard-to-heal venous leg ulcers.

Other potential markets: As a living skin substitute, Apligraf has a number of additional potential uses, including pressure ulcers, burns, epidermolysis bullosa (a genetic skin disorder) and other chronic and acute wounds. For example, we currently have a pivotal trial underway to assess the ability of Apligraf to reduce scarring following skin cancer surgery. We expect to complete this trial during 2002.

Reimbursement - In August 2000, the Centers for Medicare & Medicaid Services, or CMS, formerly known as the Health Care Financing Agency, placed Apligraf on the Outpatient Prospective Payment System list. This qualified Apligraf for reimbursement by Medicare when applied in the hospital outpatient setting, such as hospital-affiliated wound care clinics. In February 2001, the CMS classified Apligraf as a biologic for reimbursement purposes when used in a doctor's office. In January 2002, a permanent code was published for Apligraf in the American Medical Association's coding book. Apligraf is currently being reimbursed by Medicare in the hospital, hospital outpatient and doctor's office settings in all 50 states.

Bioengineered Collagen Matrix Products and Product Candidates

We have developed an acellular, collagen-based technology, called FortaFlex, that results in a strong sheet of highly purified collagen. We have optimized our FortaFlex-based products for the strength and tissue interaction requirements of specific applications. FortaFlex products are sold through our own sales force and through collaborations with Royce Medical Company and Biomet, Inc.

FortaPerm - We have used our FortaFlex technology to develop a tissue support product called FortaPerm. In June 2001, the FDA granted 510(k) marketing clearance for FortaPerm for broad use in soft tissue reinforcement applications. A 510(k) filing demonstrates that a medical device is as safe and effective as other devices that are legally marketed for the same purpose or procedure. Initial target applications for FortaPerm include the treatment of vaginal prolapse, urinary incontinence and various reconstructive and aesthetic plastic surgery procedures. Each year in the US there are approximately 350,000 uro-gynecological procedures and 200,000 plastic surgery procedures for which FortaPerm is targeted. We began commercializing FortaPerm in October 2001.

FortaGen - We have used our FortaFlex technology to develop a tissue repair product called FortaGen. In August 2001, the FDA granted 510(k) marketing clearance for FortaGen for broad use in soft tissue reinforcement applications. Initial target applications for FortaGen include complex/recurrent hernias, ostomy reinforcement and muscle flap donor sites. Each year in the US there are approximately 250,000 procedures to treat complex/recurrent hernias, 150,000 ostomy reinforcement procedures and

20,000 muscle flap donor site procedures for which FortaGen is targeted. We began commercializing FortaGen in January 2002.

PuraPly - In June 2001, the FDA granted 510(k) marketing clearance for our FortaFlex-based product, PuraPly, for use as a wound dressing in the management of acute and chronic, partial and full-thickness wounds. We have entered into a collaboration agreement with Royce Medical Company that grants Royce the right to market PuraPly to the US non-hospital market.

FortaFill - We are developing a FortaFlex-based product candidate, FortaFill, for use in soft tissue augmentation procedures, such as facial augmentation. Each year in the US, there are approximately 500,000 procedures for which FortaFill may have application.

Collaboration with Biomet, Inc. - In August 2001, we entered into a collaboration agreement with Biomet, Inc. that grants Biomet the worldwide exclusive right to distribute, market and sell co-developed FortaFlex-based orthopedic and periodontal products in exchange for a percentage of the product's net selling price. Additionally, Biomet agreed to provide us with funding for product development. The initial development project of this collaboration is a rotator cuff repair product. In March 2002, the FDA granted 510(k) marketing clearance for this product. Each year in the US, there are approximately 200,000 rotator cuff repair procedures.

Revitix

We are developing Revitix, a topical skin preparation to accelerate the rejuvenation of skin for use following laser resurfacing and deep chemical peel procedures. Each year in the US there are approximately 200,000 such procedures for which Revitix may have use. The proprietary topical formulation of Revitix includes a complex array of cytokines and growth factors that we obtain in large quantities during the manufacturing of Apligraf. Revitix provides a more complete array of growth factors than those produced by dermal fibroblasts or epidermal keratinocytes alone.

VITRIX Living Dermal Replacement Product Candidate

Deep wounds involve loss of dermis, the skin's lower layer. Dermal tissue contributes to wound healing. It also plays an important role in healing quality. Because dermal tissue, once lost, is not regenerated by the body, a need exists for living dermal replacement products. VITRIX living dermal replacement product candidate is a single layer product containing living human dermal cells, or fibroblasts, and dermal structural protein, or collagen. Because VITRIX is a single, dermal layer, it can be folded upon itself and inserted into deep wounds. Potential applications for VITRIX include deep diabetic foot ulcers and deep pressure sores, such as those extending through skin to underlying bone, ligament or tendon. We initiated a pilot trial with VITRIX in deep diabetic foot ulcers in the third quarter of 2001. A 2001 amendment to our Novartis license and supply agreement granted Novartis the right to purchase an exclusive option to negotiate terms to license VITRIX, as well as a second living dermal replacement product currently in research. We are developing other living wound healing products.

Longer-Term Research and Development Programs

We are actively seeking third party funding for several of our longer-term programs. These include: our collagen-based off-the-shelf coronary vascular graft, our liver assist device and a pancreatic islet cell research program.

Recent Developments

On February 25, 2002, we implemented a 16% reduction of workforce, which we anticipate will reduce costs by approximately $5 million per year and which primarily impacted our research and development areas for our coronary vascular graft, liver assist device and pancreatic islet cell programs. We expect this reduction to help us meet our financial goals. In the first quarter of fiscal 2002, we reserved approximately $406,000 related to severance of 37 employees.

On March 21, 2002, we completed a private placement of 100,000 shares of Series D convertible preferred stock, with rights to acquire an additional 20,000 shares of Series D convertible preferred stock and 7,241,376 shares of common stock, with warrants to acquire 3,620,686 shares of common stock to a select group of institutional investors yielding net proceeds of approximately $15,500,000.

In April 2002, Steven Bernitz was promoted to President and Chief Executive Officer. Mr. Bernitz has spearheaded our transition into a vertically integrated medical products company focused on tissue repair and regeneration. He also led our recent financing and restructuring efforts. He succeeded Michael Sabolinski, M.D., who is serving as Executive Vice President, Medical and Regulatory Affairs, and Chief Medical and Scientific Officer. In this key role, Dr. Sabolinski is leading our medical, scientific and regulatory efforts.

Risk factors
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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below before making an investment decision. You should also refer to the other information included in or incorporated by reference into our public filings with the Commission, including our consolidated financial statements and related notes. The risks and uncertainties described below are those that we currently believe may materially affect us. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial also may become important factors that affect us. If any of the following risks actually occurs, our business, operating results or financial condition could be materially adversely affected, the trading price of our common stock could decline and you could lose all or part of your investment.

We have a history of losses, we expect to continue to incur losses and our future profitability is uncertain.

The independent auditor's report for the year ended December 31, 2001 includes an explanatory paragraph stating that we have incurred recurring losses from operations, have a net capital deficiency, and have long-term debt that may become immediately due upon an event of default that raises substantial doubt about our ability to continue as a going concern.

We have incurred significant operating losses in funding the research, development, testing and marketing of our products in every year of our existence. We incurred net losses of $28,350,000 for the year ended December 31, 1999, $28,605,000 for the year ended December 31, 2000 and $30,094,000 for the year ended December 31, 2001. The extent of future losses and the time required to achieve profitability are highly uncertain, and we may never achieve a profitable level of operations or, even if we achieve profitability, we may not be able to sustain it on an ongoing basis.

If we cannot raise additional funds, we may be required to curtail or discontinue our activities.

Based upon our current forecasts, we believe that net proceeds of approximately $15,500,000 received subsequent to December 31, 2001 from the private placement of convertible preferred stock and common stock to a select group of institutional investors, together with product and other revenues, will be sufficient to finance operations through the first quarter of 2003. This projection is based on assumptions regarding our operating cash requirements and revenues from sales of Apligraf and other products, any of which could prove to be incorrect. Our research, development, manufacturing and other activities may require that we raise substantial additional funds. We may not be able to obtain additional funding on terms favorable to us or our stockholders, if at all.

Factors that may increase our cash requirements above our forecasts or require us to raise additional funds include:

- failure to achieve sales volume forecasts;
- delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- delays in commercial acceptance and reimbursement when product launches occur;
- changes in the progress of research and development programs or initiation of new programs;
- payments of accrued interest under our convertible debt outstanding in cash if we are not permitted to make such payments in stock;
- payments made under the purchase of technology assets from Baxter Healthcare Corporation that we expect to make in January 2003;

- changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies; and

- acceleration of the convertible subordinated promissory note that we issued to Novartis in October 2001, which could occur if we default on our obligations under the note.

Although we have a contractual put option to sell an additional $10 million of our securities to Novartis, we must satisfy a number of conditions in order to exercise that option. If we do not satisfy these conditions and Novartis is unwilling to waive any unsatisfied conditions, we will be unable to sell additional securities to Novartis pursuant to the put option (see "Related Party Transactions with Novartis" note). In addition, even if we satisfy the conditions, the closing would occur no sooner than 90 days following the day we send the put option exercise notice. If adequate funds are not available to us when needed, we will be required to delay, scale back or eliminate our programs or license to third parties products or technologies that we would otherwise undertake to develop ourselves and otherwise reduce our level of operations.

We have entered into collaboration agreements with Novartis and other parties to market our products and we may enter into additional collaboration agreements in the future. If these parties do not perform their obligations or terminate these agreements, it will impair our ability to commercialize our products.

We have limited experience in sales, marketing and distribution. For this reason, we have developed long-term strategic relationships with parties that have marketing and sales forces with technical expertise and distribution capability necessary to commercialize certain of our products. We entered into a license and supply agreement with Novartis pursuant to which we granted to Novartis exclusive, worldwide marketing rights for our lead product, Apligraf.

Our revenues will depend substantially upon the efforts of Novartis, which may or may not be successful in marketing and selling Apligraf. We cannot control the amount and timing of resources that Novartis may devote to marketing and selling Apligraf or its ability or willingness to continue its investment in such activities. Our license and supply agreement with Novartis will terminate when Novartis no longer has any payment obligations to us under the agreement. The payment obligations under the agreement terminate with respect to a particular country upon the later of (1) the expiration of the patent rights related to Apligraf in that country, or (2) 10 years after the first commercial sale in that country following governmental marketing approval or clearance in that country. Payment obligations with respect to sales of Apligraf in the United States would thus terminate no earlier than 2013. The license and supply agreement may be terminated sooner for various reasons, including:

- if either party commits a material breach of the terms of the agreement;

- if either party becomes insolvent or files for bankruptcy;

- if Novartis discontinues the development of Apligraf including for reasons of safety or efficacy; or

- if a competitor of Novartis acquires substantially all of our assets or 40% or more of our voting stock.

For any number of reasons, we may not be able to maintain a successful long-term strategic relationship with Novartis. If Novartis does not perform its obligations as expected or if Novartis has a strategic shift in its business focus, it would be difficult for us to continue to expand sales of or successfully commercialize Apligraf. Our failure to achieve broad use of Apligraf in the market would hurt our ability

to generate revenues and any future profits.

To the extent that we are unable to maintain our relationship with Novartis, we may need to reach agreement with another partner or may require more capital and resources to undertake a commercialization program for Apligraf at our own expense. In addition, we could encounter significant delays in introducing Apligraf into target markets or find that the commercialization of Apligraf in those markets is adversely affected by the absence of a strategic relationship with a pharmaceutical or medical products company.

We have also entered into collaboration agreements with Biomet, Inc. for the development and marketing of orthopedic and periodontal applications of our FortaFlex technology and with Royce Medical Company for the sale of our PuraPly product in non-hospital settings.

We produce Apligraf at a single location and, if we were unable to utilize this facility, we would not be able to manufacture and sell Apligraf for approximately two years.

We produce Apligraf at a single manufacturing facility located in Canton, Massachusetts. Damage to our manufacturing facility due to fire, contamination, natural disaster, power loss, unauthorized entry or other events could cause us to cease the manufacturing of Apligraf. If our manufacturing facility were destroyed, it would take approximately two years to rebuild and qualify another viable manufacturing facility, and we would not be able to sell Apligraf during the intervening period. In addition, if our manufacturing facility fails to comply with FDA and other regulatory requirements, we would be required to suspend the manufacturing of Apligraf.

If we cannot increase our manufacturing capacity for larger-scale production, we will not be able to earn substantial revenues from the sale of Apligraf.

We have been producing Apligraf for commercial sale since the second half of 1997. However, as the demand for Apligraf increases, we must further transition from small-scale to full-scale production of our products. If we do not make the full-scale transition successfully, we will not be able to satisfy the demand for our products and our results of operations will be hurt.

Because the manufacturing process for Apligraf is complicated and time-consuming, we may experience problems that would limit our ability to manufacture and sell Apligraf, which would negatively impact our results of operations.

As with any manufactured product, problems can occur during our production processes for Apligraf. These problems can result in increased product scrap, which can reduce our operating margins. These problems could also require us to delay Apligraf shipments, recall previously shipped product or be unable to supply Apligraf for a period of time, all of which could negatively impact our results of operations. We have on occasion instituted product recalls, which were not material. Contamination or defects could result in a material recall in the future, which could adversely affect our results of operations.

Our markets are competitive and our competitors could develop more effective products.

We are engaged in the rapidly evolving and competitive field of tissue engineering for the treatment of skin wounds and other medical needs. Our competitors in the field of wound care include tissue engineering companies, xenotransplant companies, wound care divisions of major pharmaceutical companies and other pharmaceutical, biotechnology and medical products companies using traditional technologies to develop products for wound care. Three of our competitors are Ortec International, Inc., Advanced Tissue Sciences, Inc. and Ortho-McNeil Pharmaceutical, an affiliate of Johnson & Johnson. Our FortaFlex based products compete with autologous tissue, cadaveric tissue, synthetic products, animal-derived tissue and other biomaterials. Competing companies in this field include C.R. Bard, Inc., Boston

Scientific Corporation, Cook Biotech, Johnson & Johnson and Mentor Corporation. Some of our competitors have much greater resources, research and development staffs and facilities, experience in conducting clinical trials and obtaining regulatory approvals and experience in the manufacturing, marketing and distribution of products than we do. Our competitive position is based upon our ability to:

- create and maintain scientifically-advanced technology and proprietary products and processes;
- attract and retain qualified personnel;
- obtain patent or other protection for our products and processes;
- obtain required government approvals on a timely basis;
- manufacture products on a cost-effective basis; and
- successfully market products.

If we are not successful in meeting these goals, our business could be hurt. Our competitors may succeed in developing technologies, products or procedures that are more effective than any that we are developing or that would render our technology and products obsolete, noncompetitive or uneconomical. One of our competitors, Advanced Tissue Sciences, received FDA approval in October 2001 for a tissue-engineered, living dermal substitute for the treatment of chronic diabetic foot ulcers. This product directly competes with Apligraf.

We may not successfully develop and market our products and products under development and, if we do not, we will not achieve profitability.

Our products are subject to the risks of failure inherent in the development of innovative health care technologies and the marketing of medical products based on these technologies. These risks include the possibility that:

- we may not be able to obtain third party funding for several of our longer-term research and development programs;
- our products will be found to be unsafe, ineffective or cause adverse reactions or will otherwise fail to meet or maintain applicable regulatory standards or receive necessary regulatory clearances;
- third parties will market superior or equivalent products or that our products will not gain broad acceptance by the medical community;
- our products will be difficult or uneconomical to manufacture and market on a large scale;
- our products will fail to achieve or be delayed in achieving acceptable insurance or other third-party reimbursement; or
- proprietary rights of third parties will preclude us from marketing our products.

Our business results will be hurt if we are unable to demonstrate to the medical community the efficacy, relative safety and cost-effectiveness of treating patients with our products or if our products are not accepted as alternatives to other existing or new therapies. Any future negative events or unfavorable publicity involving the use of our products could also adversely affect the acceptance of our products.

Our ability to develop, manufacture and market our products depends upon our compliance with government regulations and obtaining governmental approvals to market our products.

Our present and proposed products are subject to extensive and rigorous regulation by governmental authorities in the United States and other countries. To clinically test, produce and market medical products for human use, we must satisfy requirements established by the FDA and comparable foreign regulatory agencies. Typically, those rules require that products be approved by the government agency as safe and effective for their intended use prior to being marketed. The approval process is expensive, time consuming and subject to unanticipated delays. Our product candidates may not be approved. For example, although Apligraf is regulated as a medical device in the United States, the European Union regulates Apligraf as a drug, which may subject the product to a more extensive regulatory approval process than that in effect for medical devices. In April 2001, Novartis submitted Apligraf for marketing approval across the European Union through the European Medical Evaluation Agency, or EMEA. With our concurrence, Novartis withdrew its application for marketing approval in November 2001 to give us time to complete the portion of our manufacturing facility that would be used to produce Apligraf and to meet other European regulatory requirements. Novartis has agreed with us to use commercially reasonable efforts to resubmit the application for EMEA regulatory approval as soon as reasonably practical, but we cannot be certain when this will occur, if at all. There can be no assurance that we will obtain EMEA approval for Apligraf on a timely basis, if at all. The FDA and comparable foreign regulatory agencies may withdraw our product approvals for failure to comply with regulatory standards for unforeseen problems with the products.

We must test our products to determine their safety and efficacy before a submission may be filed with the FDA to obtain authorization to market regulated products. In addition, the FDA imposes various requirements on manufacturers and sellers of products under its jurisdiction, such as adherence to labeling, good manufacturing practices, record keeping and reporting requirements. Numerous regulations also govern the storage and marketing of our products. The FDA and foreign regulatory authorities have limited experience with some of our technology and products. As a result, our products are susceptible to requests for clinical modifications or additional supportive data, or changes in regulatory policy, which could substantially extend the test period for our products resulting in delays or rejections. Even after substantial time and expense, we may not be able to obtain regulatory product approval by the FDA or foreign authorities for a product or clinical indication. The FDA also may require post-marketing testing and surveillance programs for an approved product. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or could negatively affect the marketing of our existing products. We would not be able to commercialize our products as planned and our operating results would be hurt if:

- the regulatory agencies find our testing protocols to be inadequate;
- the appropriate authorizations are not granted on a timely basis, or at all;
- the process to obtain authorization takes longer than expected or we have insufficient funds to pursue those approvals;
- we lose previously-received authorizations; or
- we do not comply with regulatory requirements.

We are the sole-source manufacturer of Apligraf and have contracted with a third party to manufacture our FortaFlex line of products. We are required to maintain our manufacturing facility in compliance with the FDA's good manufacturing practices/quality systems regulations. Manufacturing facilities are usually subject to an FDA inspection before a new product is approved and are subject to

continual review and periodic inspection. The discovery of previously unknown problems with our or our contract manufacturer's manufacturing processes could result in restrictions on the applicable product or withdrawal of the product from the market. Foreign regulatory agencies can also impose manufacturing controls and inspections. We may not be able to maintain the necessary regulatory approvals for our manufacturing operations or manufacture our products in a cost-effective manner. If we are unable to manufacture potential products independently or obtain or retain third party manufacturing on commercially acceptable terms, our submission of products for final regulatory approval and initiation of marketing would be delayed. This, in turn, may prevent us from commercializing product candidates as planned, on a timely basis or on a profitable basis.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of those materials and waste products. In addition, we handle and dispose of human tissue. Although we believe that our safety procedures for handling these materials are adequate, we could be liable for damages if accidental contamination or injury were to occur. We do not maintain insurance for damages arising from accidental contamination or injury.

We have limited independent marketing experience and therefore may be unable to commercialize products for which we have not established collaborative relationships. If we are not successful in marketing these products, we will not realize substantial, if any, revenue from sales of these products.

We commenced the commercialization of FortaPerm in October 2001 and of FortaGen in January 2002. Prior to commencement of marketing and sales activities for our FortaFlex line of products, we had no experience in commercializing medical products independently. Due to our inexperience in commercializing our own products, we may not be successful in selling these or other products directly to doctors and hospitals without the assistance of a strategic partner. These commercialization efforts will require investments for marketing and sales infrastructure and will require us to incur additional operating expenses on an ongoing basis. If we are not successful in these commercializing efforts, we will not realize product revenues and our financial condition will be harmed.

We rely heavily upon patents and proprietary technology that we own and that we license from others. If third parties violate our intellectual property rights or those intellectual property rights that we license from others, we may not be able to compete in the market.

We rely upon our portfolio of patents, patent applications and licenses to patents and patent applications relating to living tissue products, organ assist treatments and other aspects of tissue engineering. We currently have rights in 18 patents issued in the United States, 10 patents issued in Europe and 7 patents issued in Japan. As part of our continuing interest in protecting our intellectual property rights, we have filed and are prosecuting 17 other patent applications in the United States. We license some of our technologies under an exclusive patent license agreement with the Massachusetts Institute of Technology ("MIT"). The agreement with MIT covers US patents and corresponding patents in Europe and Japan. We license one of the key US patents directed to our lead product Apligraf under the MIT agreement. This patent expires in 2006 and the other key US patent underlying the Apligraf technology, which we own, expires in 2013. Pursuant to the MIT agreement, MIT granted us an exclusive, worldwide license to make, use and sell the products covered by its patents and to practice the procedures covered by its patents. Additionally, we have purchased intellectual property related to our liver assist device program from Baxter Healthcare Corporation. This intellectual property includes two issued US patents and one pending US patent, as well as corresponding international patents.

We aggressively patent and protect our proprietary technologies. However, additional patents may not be issued to us from our domestic or foreign patent applications. Third parties may challenge,

invalidate or design around our patents. Third parties may infringe or independently develop either the same or similar technology as that covered by our patents or those patents licensed to us. Similarly, our patents may not provide us with meaningful protection from competitors and, as a result, our competitors could compete more directly with us.

In addition to our patent portfolio, we rely upon unpatented proprietary technology, know-how and trade secrets and seek to protect them through confidentiality agreements with employees, consultants and advisors. We request that any corporate sponsor with which we enter into a collaborative agreement do so as well. If these confidentiality agreements are breached, we may not have adequate remedies for the breach. In addition, third parties may independently develop or otherwise acquire substantially the same proprietary technology as our technology and trade secrets.

We have relationships with a number of academic consultants who are not employed by us. Accordingly, we have limited control over their activities and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology. The dissemination of our technology could hurt our competitive position and results of operations. To the extent that our scientific consultants independently develop inventions or processes that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to that information. We may not prevail in these disputes.

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our technology and manufacturing processes. If we are unsuccessful in protecting our intellectual property rights, sales of our products would suffer and our ability to generate revenues could be severely impacted.

Claims by third parties that our patents are invalid or that our products or production methods infringe their rights could prevent us from selling our products or subject us to substantial costs and liabilities.

Third parties may claim that our products or production methods infringe upon their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of medical technology patents involve complex legal and factual questions for which important legal principles remain unresolved. While we are not currently aware of any pending or threatened claim of infringement, our competitors or other third parties may assert in the future that our products or the methods we employ are covered by their patents. For example, we are aware of issued patents in the markets we currently serve and propose to serve that are held by third parties. We do not license or have other rights to these patents. We believe that the manufacture, use or sale of Apligraf does not and would not infringe any valid patents of these third parties and that other defenses would be available to us if a third party brought a claim relating to these patents against us. As we do not license or have other rights to these patents, if we were forced to defend infringement litigation, a court might disagree with our view and we might not be able to establish invalidity or non-infringement. In particular, establishing invalidity requires clear and convincing evidence sufficient to overcome the presumption of validity that issued patents enjoy by law.

In addition, because patent applications can take many years to issue, there may be currently pending applications of which we are unaware, that may later result in issued patents which our products may infringe. There could also be existing patents of which we are not aware that our products may infringe.

If an infringement lawsuit were to be asserted against us and we lost, a court could require us to

pay substantial monetary damages. Moreover, a court could prevent us from selling the infringing product unless we obtained a license to use the technology covered by the patents or redesigned our product to avoid infringement. A license may not be available at all or on terms acceptable to us, or we may not be able to redesign a product to avoid infringement. Modification of a product or development of a new product could require us to conduct additional clinical trials and to revise our filings with health regulatory agencies, which could be time-consuming and expensive. We would be materially harmed if we were unable to successfully defend against infringement litigation, were unable to obtain any required license or sublicense to a patent that we were held to infringe or were unable to design around the asserted patent.

If we are unable to obtain adequate sources of supply of the raw materials, components and specialized equipment needed to manufacture Apligraf, our ability to continue generating revenue from sales of Apligraf will be impaired.

We obtain the raw materials, components and specialized equipment used to manufacture Apligraf from numerous suppliers. Three components are currently obtained from sole-source suppliers. We maintain an inventory of the necessary raw materials, components and specialized equipment that we believe is sufficient to avoid a disruption in the production of Apligraf in the event of the temporary unavailability of these raw materials, components and specialized equipment. Because the FDA approval process requires manufacturers to specify their proposed materials of some components in their applications, FDA approval of a new material would be required if a currently approved material became unavailable from a supplier. If one or more of our suppliers ceased production of the necessary raw materials, components and specialized equipment of Apligraf, however, we would need time to qualify replacement suppliers and the manufacture of Apligraf could be disrupted.

The components used to manufacture Apligraf that we obtain from sole-source suppliers are (1) insulin, a growth hormone, (2) media, a liquid used to provide nutrients to Apligraf as the cells grow, and (3) transferrin, a plasma protein. If our supply of any one of these components were interrupted, we would be unable to manufacture Apligraf. We believe that it could take up to one year to qualify another supplier. We are currently attempting to qualify alternative suppliers. To date, we have not experienced difficulty in obtaining any of the components necessary to manufacture Apligraf. We believe that a number of alternate suppliers could provide the raw materials and components used to manufacture Apligraf.

The thermo-formed tray assembly that we use in the manufacturing process of Apligraf is a specialized piece of equipment that is available to us under a supply arrangement with only one manufacturing source. If we are unable to obtain adequate supplies of thermo-formed tray assemblies to meet future Apligraf manufacturing needs or if we cannot obtain those assemblies on a cost-effective basis, our operations would be hurt.

We also use collagen, a protein obtained from animal source tissue, as another significant material required to produce our products. We have developed a proprietary method of procuring our own collagen that we believe is superior in quality and strength to collagen available from commercial sources. We may not be able to obtain adequate supplies of animal source tissue, or to obtain this tissue from animal herds that we believe do not involve pathogen contamination risks, to meet our future needs or on a cost-effective basis.

Interruptions in our supply of raw materials, components and specialized equipment may occur in the future or we may have to obtain alternative vendors for these items. Any significant supply interruption could adversely affect the production of Apligraf or other products and delay our product development or clinical trial programs. These delays would have an adverse effect on our revenues.

We depend on our key personnel to manage our business and maintain our competitive position.

We are highly dependent upon the principal members of our management team. We do not have employment agreements with these key personnel. Furthermore, we do not maintain key-man life insurance for our key personnel. The loss of the services of any of our key personnel could adversely affect our ability to develop and market our products, to obtain necessary regulatory approvals, to achieve our business objectives, to raise additional funds and to attract strategic and collaborative partners. We have a search underway for a Chairman of the Board.

Because of the specialized nature of our business, our success will depend upon our ability to attract and retain highly qualified personnel. The competition for experienced personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions is intense. If we are unable to continue to attract and retain highly qualified personnel, our competitive position could be hurt.

We may incur material losses and costs as a result of product liability claims that may be brought against us and our insurance may not be sufficient to cover damages.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of medical products. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to product liability claims or product recall and possible adverse publicity. These claims could be based on, among other things, the presence of any impurity or pathogen in any of our products. Our products are derived from human and animal products, must be handled numerous times during the production process and, in the case of our living cell products, cannot be manufactured subject to final sterilization, all of which increase the risk that an impurity or pathogen could be present. Although we have product liability insurance coverage, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. In addition, we may not be able to obtain additional product liability coverage in the future at an acceptable cost. A successful claim or series of claims brought against us in excess of our insurance coverage and the effect of product liability litigation upon the reputation and marketability of our technology and products could harm our business.

Our business is subject to the uncertainty of third-party reimbursement and health care reform measures which may limit market acceptance.

In both domestic and foreign markets, our ability to commercialize our products and product candidates depends, in part, upon the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors increasingly challenge the price and cost-effectiveness of medical products. If our products are not considered cost-effective, third-party payors may limit reimbursement. Government and other third-party payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. Use of Apligraf for indications other than those approved by the FDA remains subject to uncertainties regarding third-party reimbursement. If government and third party payors do not provide adequate coverage and reimbursement levels for uses of Apligraf or any of our other products, the market acceptance of those products would be limited.

There have been a number of federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the US health care system. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for health care goods and services may take in response to any health care reform proposals or legislation. We cannot predict the effect that health care reforms may have on our business.

We may face interruptions in the production and shipping of our products due to delays or

stoppages in transportation, mail or related services.

Delays or stoppages in transportation, mail or other related services within the United States and throughout the world may prevent us from shipping our products to our customers resulting in lost sales. Because Apligraf is a living tissue and can only be stored for limited periods of time, customers typically purchase Apligraf on an as-needed basis and we must ship Apligraf using overnight carriers. The inability to ship Apligraf also results in the loss of inventory as the production of a batch of Apligraf cannot be stopped and restarted. The inability to ship our products and the resulting expense of lost inventory could have a material adverse effect on our business, results of operations and financial condition.

Our stock price has been volatile, and can fluctuate significantly based on events that are not in our control and general industry conditions. This volatility may make it more difficult to realize a gain on an investment in our stock.

The biotechnology sector is vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including us, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, but not limited to:

- lack of sales volume growth;
- clinical trial results, regulatory decisions and other product development events;
- the outcome of litigation;
- decisions relating to intellectual property rights;
- the entrance of competitive products into our market;
- changes in reimbursement policies or other practices related to the pharmaceutical industry;
- other industry and market changes or trends;
- the timing of approval and commercialization of our products;
- the results of research or scientific discoveries by us or others;
- new technological innovations;
- developments concerning technology rights; or
- public perception regarding the safety and efficacy of our products.

During the period from January 1, 2001 to April 10, 2002, the price of our common stock has ranged from $1.10 to $12.44 per share. These fluctuations can occur due to events outside of our control, regulatory actions such as government approval of products or reimbursements and general market conditions affecting the biotechnology sector or the stock market generally. Fluctuations in our financial performance from period to period, the issuance of analysts' reports and general industry and market conditions also may have a significant impact on the market price of our common stock.

If we cannot meet the American Stock Exchange maintenance rules and requirements for continued listing, the American Stock Exchange may delist our common stock, which would negatively impact the price of our common stock and the ability to sell our common stock.

Our common stock is listed on the American Stock Exchange, or AMEX. The AMEX rules provide that the AMEX will consider delisting when a company has, among other things, (a) sustained losses in two of its three most recent fiscal years and has stockholders' equity of less than $2 million or (b) sustained losses from continuing operations and/or net losses in each of its five most recent fiscal years. We currently do not satisfy these criteria. In December 2001, the AMEX agreed to continue our listing pending a review of our progress in meeting these criteria as reflected in this filing on Form 10-K. We agreed to raise additional funds in the first quarter of 2002, and to report back to the AMEX by April 2002 regarding our progress in raising capital and meeting projected operating results. We believe that the net proceeds of approximately $15.5 million from our sale of equity securities on March 21, 2002, together with the conversion of our 7% convertible promissory notes issued in 1999 and our 7% convertible promissory note issued to Novartis in 2001, would allow us to meet the stockholders' equity criterion. The consent of the holders of these notes is required to effect conversion of these notes, and the consent of the holders of the 1999 notes may require the conversion price applicable to those notes ($14.50, subject to adjustment) to be modified, which modification would require Novartis' consent. If we are unable to obtain such consents, we will need to raise additional capital to meet the stockholders' equity criterion. We expect Apligraf commercial sales to continue to increase, which combined with the 16% reduction of workforce which we anticipate will reduce costs by approximately $5 million per year, implemented on February 25, 2002, will help us achieve break-even results in the future.

We cannot provide any assurance that our common stock will remain listed on the AMEX or that we will not be delisted if we fail to meet these listing criteria. In the event our common stock is delisted from the AMEX, it would be more difficult to trade in our common stock and more difficult to obtain accurate, current information concerning market prices for our common stock. In addition, we would find it more difficult to raise equity financing if our common stock is delisted.

If we default on our obligations under the convertible subordinated promissory note that we issued to Novartis, we may be required to repay to Novartis the full principal amount of the note, together with interest, and we may incur additional financial obligations to Novartis.

Under the terms of the convertible subordinated promissory note that we issued to Novartis as of September 28, 2001, Novartis may declare the full principal amount of the note, together with all accrued but unpaid interest on the note and other amounts that we owe to Novartis on the date of acceleration, to be immediately due and payable in cash upon the occurrence of an event of default. As of March 25, 2002, there was $10 million in principal amount outstanding under the note, which is due on March 29, 2004. Interest on the note accrues at 7% annually and is payable on September 30 and March 31 of each year. Although we are entitled to deliver shares of our common stock in satisfaction of the note at any time after March 31, 2002, we must satisfy a number of conditions, some of which cannot be satisfied without a waiver from Novartis. Any one of the following events will constitute an event of default under the note:

- our default in the timely payment to Novartis of the principal amount of, interest on or liquidated damages in respect of the note;
- any representation or warranty that we made to Novartis proves to have been incorrect when we made it under the note or the agreement under which the note was issued;
- our failure to observe or perform any covenant or agreement under, or our breach of, the note or the agreement pursuant to which the note was issued which is not remedied by us within 30 days of notice thereof;

- any bankruptcy, insolvency or reorganization proceedings involving us or any of our subsidiaries; or

- the delisting or suspension of our common stock from trading on the AMEX without being relisted for a period of 30 trading days.

If we default on our obligations under the terms of the note and are required to repay to Novartis all or a large portion of the amounts owed under the note, our financial condition and results of operations would be significantly adversely affected.

Our anti-takeover provisions may deter potential acquirors and may depress our stock price.

We, as a Delaware corporation, are subject to the General Corporation Law of the State of Delaware, including Section 203, an anti-takeover law enacted in 1988. In general, Section 203 restricts the ability of a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder. As a result of the application of Section 203 and provisions in our restated certificate of incorporation, as amended, and by-laws, potential acquirors may be discouraged from attempting to acquire us, thereby possibly depriving our stockholders of acquisition opportunities to sell or otherwise dispose of our stock at above market prices typical of these acquisitions.

We have also adopted a shareholder rights plan, which gives holders of our common stock the right to purchase shares of our Series B Junior Participating Preferred Stock if a potential acquiror purchases 15% or more of our outstanding common stock or plans to make a tender offer to purchase 30% or more of our outstanding common stock. The existence of this plan may make it more difficult for a third party to acquire control of us.

We are authorized to issue up to 1,000,000 shares of preferred stock, $1.00 par value per share, and to determine the price, privileges and other terms of these shares. The issuance of any preferred stock with superior rights to our common stock could reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with or sell our assets to a third party, thereby preserving control of us by present owners and management and preventing the holders of our common stock from realizing a premium on their shares.

The value of your securities may decrease if other security holders exercise their options and warrants or if their debt is converted.

At March 25, 2002, 44,316,276 shares of our common stock were outstanding, which excludes 250,000 treasury shares. We have reserved an additional 20,248,445 shares of our common stock for issuance under our employee stock purchase plan and upon the exercise of outstanding stock options and warrants, the exercise of stock options available for grant under our option plans, the conversion of issued convertible notes and issued Series D convertible preferred stock and Series D convertible preferred stock issuable upon exercise of rights sold in a private placement. We plan to grant additional options in the future. If any of these securities are exercised or converted, investors may experience dilution in the market value and earnings per share of the common stock into which these securities are convertible.

Related Party Transactions with Novartis

We believe Novartis to be our related party because it has approximately a 7.4% equity investment (assuming conversion of their 7% Convertible Subordinated Note) as of December 31, 2001 and it is the sole distributor for our lead product, Apligraf.

In January 1996, we entered into a collaborative agreement with Novartis granting Novartis exclusive global marketing rights to Apligraf. Under the agreement, we have received equity investments, non-refundable research, development and milestone support payments, product payments, funding for publication study programs and funding for European regulatory filing for Apligraf marketing approval. Product and other funding for programs are included under the captions "Product sales to related party" and "Other revenues" in our financial statements.

In February 2001, we amended our collaborative agreement with Novartis, effective January 2, 2001. The amended agreement:

- Grants Novartis the right to purchase an exclusive option to negotiate terms to license Organogenesis's product Vitrix and also a second living dermal replacement product currently in research;
- Provides Organogenesis with significantly higher payments for units of Apligraf;
- Grants Organogenesis the right for three years to sell, at its discretion, to Novartis up to $20 million in equity or convertible debt, of which $10 million was received in October 2001;
- Includes funding support from Novartis to upgrade Organogenesis's manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union;
- Includes funding support for Apligraf clinical development activities (e.g., to further broaden its approved uses); and
- Includes development funding support for each living dermal replacement product for which Novartis purchases an option to commence licensing negotiations.

We supply Novartis's global requirements for Apligraf and receive a product payment based on net product sales. Receivable from related party consists of amounts due on product sales to Novartis, funding of certain programs by Novartis and reimbursement of certain test costs related to the manufacturing of the product. Novartis is billed monthly for payments due on product sales and on an as incurred basis for other billings.

On June 29, 2001, we exercised a $10,000,000 security option with Novartis, which closed on October 16, 2001. The security sold was a 7% Convertible Subordinated Note in the principal amount of $10,000,000 with a maturity date of March 29, 2004. The Note may be converted into shares of common stock at an adjusted conversion price of $4.49 per share (subject to further adjustment dependent on common stock trading limitations or Novartis conversion rights change) at any time by Novartis or by us, subject to certain conditions, at any time after March 31, 2002. The conversion price of the Note was below the trading market price on the day the Note was issued. As a result of this beneficial conversion feature, we recorded interest expense of $15,000 during the fourth quarter of 2001 and will record $342,000 of added interest expense over the remaining period the Note is outstanding. Interest on the Note accrues at 7% annually, payable in cash, common stock (at the average market price for the twenty trading days immediately proceeding the due date) or any combination thereof, at our option, subject to certain conditions, on September 30 and March 31. Principal amounts due under the Note, including accrued interest, may become immediately payable in cash if an event of default occurs, defined as: any default in the timely payment of principal, interest or liquidated expenses under the Note; any representation or warranty made to Novartis which proves to have been incorrect when we made it under the Note or the February 2001 Securities Purchase Agreement with Novartis or related documents; any failure to perform any covenant or agreement, or otherwise commit a breach under, the Note or the February 2001 Securities Purchase Agreement which is not remedied by us within 30 days of notice; any bankruptcy, insolvency or

reorganization proceedings involving us or any of our subsidiaries; and the delisting or suspension of our common stock from trading on the AMEX without being relisted or having such suspension lifted within 30 trading days.

Additionally, if we fail to deliver to Novartis registered shares of our common stock on conversion of the Note, we will be required to pay to Novartis the greater of (a) actual expenses incurred by Novartis as a result of Novartis's need to purchase shares of common stock to satisfy its delivery requirements, and (b) on each date the conversion is not timely effected, an amount equal to one percent (1%) of the product of the number of shares of common stock not issued to Novartis on a timely basis and the closing bid price of our common stock on the last date that we could have issued shares of our common stock to Novartis without violating our delivery obligations.

As a result of previous equity investments made in prior years and not including conversion of the 7% Convertible Subordinated Note, Novartis holds approximately 1.8% of our outstanding shares as of December 31, 2001. Assuming conversion of their 7% Convertible Subordinated Note, Novartis would hold approximately 7.4% of our outstanding shares as of December 31, 2001.

As of December 31, 2001, Novartis approved funding support of $9,266,000 for facility upgrades and for the European manufacturing suite in the US facility. All payments made have been recorded as deferred revenue for the year ended December 31, 2001. Revenue will be recognized over the period that the completed manufacturing facility is used for production of Apligraf to be sold to Novartis, which is expected to start later in 2002. We have incurred expenditures of $485,000 and $8,781,000 for the years ended 2000 and 2001, respectively, relating to this funding support.

During the year ended December 31, 2001, Novartis agreed to provide funding for support activities related to the regulatory filing for Apligraf marketing approval across the European Union. We received $782,000, of which $336,000 was recorded as other revenues for the year ended December 31, 2001, with the remainder included in deferred revenue from related party at December 31, 2001. During the first quarter of 1999, Novartis agreed to provide funding for publication study programs to be conducted by us. We have recorded other revenues of $162,000 and $19,000 for the years ended December 31, 2000 and 2001, respectively, relating to the initiation of these programs.

The following table summarizes by year all equity and convertible debt investments, non-refundable research, development and milestone support payments received from Novartis. Product and other payments are included under the captions "Product sales to related party" and "Other revenues" in our financial statements.

| | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 |
|---|---|---|---|---|---|---|
| Equity investments | $ 5,000,000 | $ - | $ 6,000,000 | $ - | $ - | $ - |
| Convertible note | - | - | - | - | - | 10,000,000 |
| Up front non-refundable research and development support payments | 6,500,000 | 2,500,000 | 750,000 | - | - | - |
| Funding support for facility upgrades | - | - | - | - | 485,000 | 8,781,000 |
| Non-refundable milestone payments | - | - | 6,000,000 | - | 5,000,000 | - |
| Total | $11,500,000 | $ 2,500,000 | $12,750,000 | $ - | $ 5,485,000 | $18,781,000 |

Research Agreements

We have entered into various collaborative research agreements that are generally funded over a one or two-year period. Each agreement is reviewed at least annually and the amounts to be funded for the next period are then determined. Either party may cancel the agreement upon advance written notice.

Total payments made by us to third parties under these agreements were $662,000, $604,000 and $208,000 for 1999, 2000 and 2001, respectively.

Research and Development

On February 25, 2002, we implemented a 16% reduction of workforce, which we anticipate will reduce costs by approximately $5 million per year and which primarily impacted our research and development areas for our coronary vascular graft, liver assist device and pancreatic islet cell programs. We are seeking third party funding for these programs. We expect this reduction to help us meet our financial goals. In the first quarter of fiscal 2002, we reserved approximately $406,000 related to severance of 37 employees.

For 1999, 2000 and 2001, research and development expenses were $19,066,000, $17,511,000, and $16,498,000, respectively, which consist of costs associated with research, development, clinical and process development, facilities and engineering support used in R&D. All amounts expended were for company-sponsored research and development.

Employees

As of March 25, 2002, we had 182 full-time employees: 132 in manufacturing, operations and quality assurance; 12 in Research and Clinical; and 38 in Selling, General and Administrative. We have established a stock option plan providing equity incentives, an employee stock purchase plan and a 401(k) plan for all full-time employees. We believe that, through equity participation, attractive fringe benefit programs and the opportunity to contribute to the development and commercialization of new products using new technology, we will continue to be able to attract highly-qualified personnel.

Item 2. PROPERTIES

We occupy our main office and manufacturing premises under a facility lease for 79,500 square feet of space in Canton, Massachusetts at an annual average base rent of approximately $790,000, plus operating expenses, that expires on September 30, 2004. This lease has three options to extend the term for an additional five years per option. Taxes, insurance and operating expenses are our responsibility under the terms of the lease. We entered into another facility lease for approximately 20,500 square feet of additional office and warehouse space in Canton, Massachusetts at an annual average base rent of approximately $138,500, plus operating expenses, that expires on December 5, 2004. This lease has three options to extend the term for an additional five years per option. In total, we currently lease 100,000 square feet of space.

We believe that current facilities will adequately support manufacturing needs and research and development activities through the end of 2003 and beyond.

Item 3. LEGAL PROCEEDINGS

None

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the American Stock Exchange under the symbol ORG. On March 25, 2002, there were 725 shareholders of record of our common stock. The table below lists the high and low quarterly range of reported closing prices of our common stock during the past two years.

| | 2000 | | 2001 | |
|---|---|---|---|---|
| | High | Low | High | Low |
| First Quarter | $19.50 | $ 8.00 | $12.44 | $ 7.65 |
| Second Quarter | 12.69 | 8.25 | 9.40 | 6.85 |
| Third Quarter | 16.27 | 11.11 | 9.01 | 5.00 |
| Fourth Quarter | 13.81 | 6.80 | 5.85 | 3.88 |

On March 25, 2002, the last sale price of the common stock was $1.57. We have never paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not expect to pay any cash dividends in the foreseeable future. As a result, an investor will only recognize an economic gain on an investment in our stock from an appreciation in the price of our stock.

Item 6. SELECTED FINANCIAL DATA

The following table sets forth consolidated financial data with respect to the Company for each of the five years in the period ended December 31, 2001. The selected financial data for each of the five years in the period ended December 31, 2001 have been derived from the consolidated financial statements of the Company. The information below should be read in conjunction with the consolidated financial statements (and notes thereon) and "Management's Discussion and Analysis of Financial Condition and Results of Operations", included in Item 7.

| | For the Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 1997 | 1998 | 1999 | 2000 | 2001 |
| | (in thousands, except per share data and number of employees) | | | | |
| Revenues | $ 3,029 | $ 7,939 | $ 2,676 | $ 10,240 | $ 10,882 |
| Net Loss | (19,807) | (14,031) | (28,350) | (28,605) (1) | (30,094) |
| Net Loss Per Common Share | (0.70) | (0.48) | (0.93) | (0.85) (1) | (0.86) |
| Working Capital | 4,843 | 15,541 | 2,981 | 6,226 | (2,509) |
| Capital Expenditures | 1,069 | 2,464 | 5,767 | 2,912 | 1,438 |
| Capital Expenditures Reimbursed from Related Party | - | - | - | 485 | 8,781 |
| Total Assets | 13,780 | 26,710 | 27,305 | 27,872 | 27,370 |
| Total Long-Term Debt | - | - | 22,287 | 18,835 | 26,232 |
| Stockholders' Equity (Deficit) | 11,523 | 23,239 | (6,974) | (3,784) | (21,768) |
| Number of Employees | 137 | 186 | 208 | 232 | 239 |
| Pro forma amounts assuming SAB 101 is applied retroactively: | | | | | |
| Revenues | 1,344 | 8,222 | 3,733 | | |
| Net Loss | (21,492) | (13,748) | (27,293) | | |
| Net Loss Per Common Share | (0.76) | (0.47) | (0.90) | | |

(1) Includes the cumulative effect of a change in accounting principle related to all up front non-refundable research and development support payments recognized in prior periods of $6,342,000 or $0.19 per share (basic and diluted) for 2000, in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101).

Item 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## Overview of Organogenesis Inc.

Organogenesis Inc. designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We were the first company to develop, manufacture and gain US Food and Drug Administration ("FDA") approval for a mass-produced product containing living human cells. Our lead product, Apligraf(R) living skin substitute, is FDA approved and marketed in the US for two uses: treatment of healing-resistant venous leg ulcers, approved in May 1998, and treatment of healing-resistant diabetic foot ulcers, approved in June 2000. Novartis Pharma AG ("Novartis") has exclusive global Apligraf marketing rights. Our FortaFlex(TM) bioengineered collagen matrix product line includes FortaPerm(TM) tissue support product and FortaGen(TM) tissue repair product. Both FortaPerm and FortaGen are being sold by our sales and marketing team.

## Apligraf(R) Living Skin Substitute

Our lead product, Apligraf living skin substitute, is FDA approved and marketed in the US for two uses: treatment of healing-resistant venous leg ulcers, approved in May 1998, and treatment of healing-resistant diabetic foot ulcers, approved in June 2000. Novartis has exclusive global Apligraf marketing rights. Decisions made at the national and regional level have expanded access to Apligraf by Medicare-insured patients, and the product is now being reimbursed by Medicare in all fifty states. Apligraf is also available in select international markets.

A pivotal trial is underway to assess the ability of Apligraf to reduce scarring after skin cancer surgery. We expect to complete this trial in 2002. As a skin substitute, we believe Apligraf has a number of additional potential uses, including treating pressure ulcers, burns, epidermolysis bullosa (a genetic skin disorder) and other chronic and acute wounds.

## Bioengineered Collagen Matrix Products and Product Candidates

We are leveraging our FortaFlex bioengineered collagen matrix technology into a family of products. In October 2001, we launched FortaPerm tissue support product and in January 2002, we launched FortaGen tissue repair product. FortaPerm and FortaGen are being marketed by our own sales and marketing team. Royce(R) Medical Company has marketing rights for the US non-hospital market for our PuraPly wound dressing. In 2001, we entered into a collaboration agreement with Biomet, Inc. which initially grants Biomet the right to co-develop and market FortaFlex-based orthopedic and periodontal products in exchange for royalties. In March 2002, the FDA granted 510(k) marketing clearance for our rotator cuff repair product. This is the first product developed under our collaboration with Biomet.

Apligraf(R) is a registered trademark of Novartis.
Royce(R) is a registered trademark of Royce(R) Medical Company.

Research and Development Programs

We are developing a FortaFlex-based product candidate, FortaFill, for use in soft tissue augmentation procedures, such as facial augmentation. We are also developing Revitix Regenerative Skin Complex, for use following laser resurfacing and chemical peel procedures. Our research and development pipeline also includes a living dermal replacement product candidate, VITRIX(TM). We have initiated a clinical study of VITRIX in the treatment of deep diabetic foot ulcers. We are developing additional living wound healing products, which are currently in research.

We are actively seeking third party funding for several of our longer-term programs. These include: our collagen-based off-the-shelf coronary vascular graft, our liver assist device, and a pancreatic islet cell research program.

On February 25, 2002, we executed a 16% reduction of workforce, which primarily impacted our research and development areas and which we anticipate will reduce costs by approximately $5 million per year. We expect this reduction to help us meet our financial goals. In the first quarter of fiscal 2002, we reserved approximately $406,000 related to severance of 37 employees.

Critical Accounting Policies

We prepare our financial statements under generally accepted accounting principles that require us to make estimates and assumptions that affect amounts reported and the related disclosures. Actual results could differ from those estimates. Certain prior year amounts have been reclassified to conform to the current year presentation. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Inventory Valuation and Cost of Product Sales

A number of internal and external factors affect our inventory valuation and cost of product sales to related party, including material costs, labor and overhead calculations. These estimates of costs, especially calculation of our overhead rates, are subjective and may change in the future. We expect that we will have to revise our estimates of costs in the future based on actual production activity as we continue to modify our manufacturing processes. Inventory is valued at the lower of cost or market, with estimates of reserves for net realizable value and obsolescence evaluated quarterly. If conditions change, or if we use different assumptions in calculating our inventory reserves or our labor and overhead rates, it is likely that materially different amounts recorded for inventory and cost of product sales would be reported in our financial statements.

Long-Lived Assets

Our policy regarding long-lived assets is to evaluate the recoverability or usefulness of these assets when the facts and circumstances suggest that these assets may be impaired. This analysis relies on a number of factors, including changes in strategic direction or market emphasis, business plans, regulatory developments, economic and budget projections, and operating results. The test of recoverability or usefulness is a comparison of the asset value to the present value of its expected cumulative net operating cash flow or the asset's usefulness in research and development programs or operations over the remaining life of the asset. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized.

Our long-lived assets include cell banks which contain the living human cell raw materials used in the manufacturing of Apligraf and are cryopreserved for extended periods of time greater than one year. We evaluate the usefulness of this asset and reserve for any cell banks which may be scrapped in the future, however, the manufacturing process could change, which may result in higher yielding cell banks and in turn, may obsolete a greater number of previously manufactured cell banks. This could result in further